UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,464	07/29/2003	Jon Elliot Adler	100337/54260US	4703

23911 7590 11/01/2004

CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON, DC 20044-4300

EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,464	ADLER ET AL.	
	Examiner	Art Unit	
	Zachary C Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-67 are pending in the instant application.

Advisory Information

Applicant is advised that claims 12 and 13 are placed with Invention IV, drawn to a method of producing an antibody, even though they depend from claims 10 and 8, respectively.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C 121:

I. Claims 1-3 and 16-26, drawn to isolated T2R76 nucleic acid molecules, and systems of heterologous expression, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3, and 69.1, for example.

II. Claim 4, drawn to a method of detecting a T2R76 nucleic acid in a comprising contacting a biological sample by hybridization, classified in class 435, subclass 6, for example.

III. Claims 5-10, drawn to T2R76 polypeptides, classified in class 530, subclass 350, for example.

IV. Claims 11-14, drawn to an antibody that specifically recognize T2R76 polypeptides, and a method of producing an antibody, classified in class 530, subclass 388.22, for example.

V. Claim 15, drawn to a method of determining the level of a T2R76 polypeptide comprising contacting a biological sample with an antibody, classified in class 435, subclass 7.1, for example.

VI. Claims 27-37 and 45-48, drawn to a method of identifying a modulator of T2R76 polypeptide function, classified in class 435, subclass 7.1 and class 436, subclass 401, for example.

VII. Claims 38-39 and 49-50, drawn to a modulator of T2R76 function, classified in classification dependent on compound structure.

VIII. Claims 40-44 and 51-62, in so far as they drawn to a method for reducing bitter taste perception in a subject, classified in classification dependent upon compound structure.

IX. Claims 40-44, 51-56 and 63-67, in so far as they are drawn to a method for enhancing bitter taste perception in a subject, classified in classification dependent upon compound structure.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can be used in a method of detecting T2R76 nucleic acid in a biological sample, but the nucleic acids can also be used in a method recombinantly producing the protein.

Inventions I, III, IV, and VII are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polynucleotide of **Invention I** and the polypeptide of **Invention III** are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of

the encoded polypeptide. Furthermore, searching the inventions of **Inventions I and III** together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of **Inventions I and III** have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides that would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers that had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of **Invention I** would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of **Invention** I. As such, it would be burdensome to search the inventions of **Inventions I and III**.

The polypeptide of **Invention III** and the antibody of **Invention IV** are patentably distinct for the following reasons: while the inventions of both **Inventions III and IV** are polypeptides, in this instance, the polypeptide of **Invention III** is a single chain molecule, whereas the polypeptide of **Invention IV** encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of **Invention III** and the antibody of **Invention IV** are structurally distinct molecules; any relationship between a polypeptide of **Invention III** and an antibody of **Invention IV** is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide. In this case, the polypeptide of **Invention III** is a large molecule that contains potentially hundreds of regions to which an antibody must bind, whereas the antibody of **Invention IV** is defined in terms of its binding specificity to a small structure within **the disclosed SEQ ID NO**. Thus, immunization with the polypeptide of **Invention III** would result in the production of antibodies outside the scope of **Invention IV**.

Therefore, the polypeptide and antibody are patentably distinct. Furthermore, searching the inventions of **Invention III** and **Invention IV** would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody which to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of **Invention IV**. Furthermore, antibodies which bind to an epitope of a polypeptide of **Invention III** may be known even if a polypeptide of **Invention III** is novel. In addition, the technical literature search for the polypeptide of **Invention III** and the antibody of **Invention IV** is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

The polynucleotide of **Invention I** and the antibody of **Invention IV** are patentably distinct for the following reasons: the antibody of **Invention IV** includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of **Invention IV** which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of **Invention I** will not encode an antibody of **Invention IV**, and an antibody of **Invention IV** cannot be encoded by a polynucleotide of **Invention I**. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of **Inventions I** and **IV** would impose a serious search burden since a search of the polynucleotide of **Invention I** would not be used to determine the patentability of an antibody of **Invention IV** and vice-versa.

The modulator of T2R76 polypeptide activity of Invention VII is a structurally and functionally different compound that the nucleic acids of Invention I, the polypeptide of Invention III, and the antibodies of Invention IV. Invention VII is related to Invention III in that Invention VII is drawn to compounds that modulate the function of polypeptide of Invention III. Each invention is independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

Inventions II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Invention III and the antibodies and the method of producing antibodies of Invention IV are not used in the method of detecting a *T2R76* nucleic acid by hybridization.

Inventions I and V are unrelated. In the instant case the nucleic acids of Invention I are not used in the method of detecting a T2R76 polypeptide.

Inventions I, IV, and VI are unrelated. In the instant case the nucleic acids of Invention I and the antibodies of invention IV are not used in the method of identifying a modulator of T2R76 polypeptide function.

Inventions I, III, and IV are unrelated to inventions VIII and IX. The T2R76 nucleic acids, polypeptides and antibodies and not used in either a method of reducing or a method of enhancing bitter taste.

Invention VII is unrelated to each of inventions IV and V. The compound that modulates T2R76 function is not used in the methods of detecting T2R76 nucleic acids or polypeptide.

Inventions III and IV are each related to Invention V as product and process of use. In the instant case the T2R76 polypeptides and antibodies can each be used in a method of detecting T2R76 polypeptide in a biological sample, but the polypeptides can also be used in a method of screening for compounds that bind the polypeptide, and the antibodies can also be used in a method of affinity purification of the protein.

Invention III is related to Invention VI as product and process of use. In the instant case the T2R76 polypeptide can be used in a method of identifying a modulator of T2R76 function, but the T2R76 polypeptide can also be used in a method of generating antibodies.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions II, V, VI, VIII and IX are directed to methods that are distinct both physically and functionally, and are not required one for the other. While, Inventions VIII and IX are related in that each is a method for modulating bitter taste perception in a subject, Inventions VIII and IX are independent and distinct, each from each other, because Invention VIII is drawn to compounds that reduce bitter taste, and Invention IX is drawn to compounds that enhance bitter taste. Because these method goals are distinct and functionally in opposition, the compounds with these desired goals will be structurally and functionally distinct, and require a search and consideration that is not co-extensive. Each method uses compounds that possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged

Invention VII is related to invention VI in that modulators of T2R76 polypeptide function are a presumably small subset of all the compounds that will be screened in the method of identifying a modulator. However, the method of identifying can also be performed with compounds that are not modulators of T2R76 polypeptide function.

Invention VII is related to each of Inventions VIII and IX as product and process of use. In the instant case the modulator of T2R76 polypeptide function can be used in methods of reducing or enhancing bitter taste in a subject, the modulator could also be used in a method of treatment of an individual with aberrant T2R76 polypeptide function.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search

required for each Invention is not required for the other Inventions because each Invention requires a different non-patent literature search due to each Invention comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Further restriction within Group III:

If Group III is elected, in addition to the above restriction requirement, a further restriction is required, as follows: Applicant must elect either the polypeptide of SEQ ID NO: 2, or a single combination of the polypeptide of SEQ ID NO: 2 and one other T2R protein selected from group consisting of T2R51, T2R54, T2R55, T2R461, T2R63, T2R64, T2R65, T2R67, T2R71, T2R75, T2R59, T2R33, and each of the T2R proteins disclosed on page 12 of the specification.

Although the classifications for the proteins are overlapping, each represents a patentably distinct product, having different sequences and requiring separate sequence searches.

Applicants are advised that this is not a species election.

Rejoinder under Ochiai/Brouwer

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined

for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Robin L. Teskin on 10/22/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eileen B. O'Hara

zch

EILEEN B. O'HARA
PATENT EXAMINER